

EU Declaration of Conformity




for the COVVI Hand - Straight Wrist

We herewith declare, under the manufacturer's sole responsibility, that the products described in this document are in conformity with the relevant requirements of **Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices and Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)** and are manufactured and released according to the provision of the quality management system in force on the date of issue of this declaration and the CE Mark may be affixed.

PRODUCT NAME:	COVVI Hand - Straight Wrist
LEGAL MANUFACTURER:	COVVI LTD, Unit 4 (Direct House), Quayside Business Park, George Mann Road, Leeds, LS10 1DJ, UK
SINGLE REGISTRATION NUMBER (SRN)	GB-MF-000033926
BASIC UDI-DI	506072613GMN027XE
GLOBAL MEDICAL DEVICE NOMENCLATURE CODE	41497
EUROPEAN MEDICAL DEVICE NOMENCLATURE CODE	Y061899
APPLICABLE LEGISLATIONS AND STANDARDS	As per Appendix I – Applicable Legislations and Standards
CONFIGURATIONS & VARIANTS:	As per Appendix II – Product Listing/Schedule
INTENDED PURPOSE:	The COVVI Hand - Straight Wrist is an external, motor-driven prosthetic hand with a Straight Wrist designed to assist individuals with unilateral or bilateral upper limb deficiencies. Specifically crafted with anatomically correct dimensions, the COVVI Hand - Straight Wrist facilitates activities of daily living through controlled movement of programmed grip patterns.
MEDICAL DEVICE CLASSIFICATION	Class I [Rule 13]
NOTIFIED BODY	N/A
CE CERTIFICATE	N/A
EU AUTHORISED REPRESENTATIVE:	Advena Limited Tower Business Centre, 2 nd Fl., Tower Street, Swatar, BKR 4013 Malta
EU AUTHORISED REPRESENTATIVE SRN:	MT-AR-000000234
MEDICAL DEVICE REGULATION ASSESSMENT ROUTE	In conformity with Annexes II and III, the Declaration of Conformity has been drawn up in accordance with Article 19 of Regulation (EU) 2017/745.

Name Simon Pollard **Position** Group CEO

Signed  **Date** 19-Feb-2026 **Place** Leeds, United Kingdom

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Our statements in this document regarding compliance do not extend to, or apply to any product subjected to unintended contamination, misuse, neglect, or accident.

COVVI

COVVI House, 4 Quayside Business Park, George Mann Road, Leeds, LS10 1DJ
Switchboard: +44 (0)203 9499 500 Website: www.covvi.com Website: www.covvi-robotics.com

Registered in England No: 10932714 | VAT Registration No: 278 6409 59 | Registered Office Address: Direct House, 4 Quayside Business Park, Hunslet, Leeds, West Yorkshire, LS10 1DJ

Appendix I – Applicable Legislations and Standards

This product complies with the essential requirements of the following regulations and standards.

1. Regulations

- **UK MDR 2002** – The Medical Devices Regulations 2002
- **EU MDR 2017/745** – Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
- **21 CFR** – Title 21 Code of Federal Regulations (Parts 800-1299 as applicable)
- **Ukrainian Technical Regulations**- Resolution of the Cabinet of Ministers of Ukraine No. 753 (“On Approval of the Technical Regulation on Medical Devices”)
- Australia Regulation- **Therapeutic Goods Administration**
- New Zealand Regulation- **Medsafe** (New Zealand Medicines and Medical Devices Safety Authority)
- Health Canada- **Medical Devices Regulations** (SOR/98-282)
- Argentina Regulations (**ANMAT**)- The National Administration of Drugs, Foods and Medical Devices
- Mexico (**COFEPRIS**)- Federal Commission for the Protection against Sanitary Risk
- Brazil Regulations (**ANVISA**, RDC No. 751/2022)- ANVISA (The National Health Surveillance Agency)
- Dubai (Dubai Health Authority (DHA))- Ministry of Health and Prevention (**MOHAP**)
- Federal Law No. 323-FZ, Article 38- Ministry of Health of the Russian Federation (**Minzdrav**)
- Swissmedic – **Swiss Agency for Therapeutic Products**- Medical Devices Ordinance (MedDO, SR 812.213)

2. Standards

- **ISO 13485** – Medical devices. Quality management systems. Requirements for regulatory purposes
- **ISO 14971** – Medical devices. Application of risk management to medical devices
- **ISO/TR 24971** – Medical devices. Guidance on the application of ISO 14971
- **EN ISO 15223-1** – Medical devices. Symbols to be used with information to be supplied by the manufacturer. General requirements
- **EN ISO 20417** – Medical devices, Information to be supplied by the manufacturer
- **IEC 62304**– Medical device software- Software life cycle processes
- **BS EN 62366-1** – Medical devices. Application of usability engineering to medical devices
- **IEC 60601-1** – Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
- **BS EN 60601-1-2** – Medical electrical equipment - General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
- **IEC 60601-1-11**– Medical electrical equipment. Part 1-11: General requirements for basic safety and essential performance
- **EN ISO 10993-1** – Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process
- **ISO 639** – Language code, Codes for the representation of names of languages

3. Unharmonized standards

- **ISO/TC 168** – Prosthetics and orthotics
- **ISO 29783 series** – Prosthetics and orthotics
- **ISO 22523** – External limb prostheses and external orthoses: Requirements and test methods
- **ISO 8548 series** – Prosthetics and orthotics
- **ISO 8549 series** – Prosthetics and orthotics
- **ISO 13405 series** – Prosthetics and orthotics

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4. Test Reports & Certification

This document supported by the following test reports.

- **EMC Test Report No: 13400TR1– Eurofins E&E UK**
- **Radio Testing Report No: C13440TR1– Eurofins E&E UK**
- **EMC Test Certificate No: 13469TC1 – Eurofins E&E UK**
- **Safety Testing Report No: C13411TR1 – Eurofins E&E UK**
- **60601-1 Safety Testing Certificate No: C13622TC1 - Eurofins E&E UK**
- **60601-1-2 Test Certificate No: 13403TC1 - Eurofins E&E UK**
- **Ingress Protection Test Report No: CML-IPTR-18072-A – Eurofins E&E UK**
- **Ingress Protection Certificate No: CML-IPTC-18072-A – Eurofins E&E UK**
- **Environmental Test Report No: 105266 - Alphatech Ltd**
- **Environmental Test Certificate No: 105266 - Alphatech Ltd**

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Appendix II – Product Listing/Schedule

Product Code:	Description:	UDI-DI
CVSLSQBLRG	Straight Wrist Small Left Hand - Black Glove, Rose Gold Cover	5060726132435
CVSLSQBLCA	Straight Wrist Small Left Hand - Black Glove, Carbon Cover	5060726132442
CVSLSQBLTG	Straight Wrist Small Left Hand - Black Glove, Titan Grey Cover	5060726132459
CVSLSQBLWH	Straight Wrist Small Left Hand - Black Glove, White Cover	5060726132466
CVSRSQBLRG	Straight Wrist Small Right Hand - Black Glove, Rose Gold Cover	5060726132473
CVSRSQBLCA	Straight Wrist Small Right Hand - Black Glove, Carbon Cover	5060726132480
CVSRSQBLTG	Straight Wrist Small Right Hand - Black Glove, Titan Grey Cover	5060726132497
CVSRSQBLWH	Straight Wrist Small Right Hand - Black Glove, White Cover	5060726132503
CVSLMQBLRG	Straight Wrist Medium Left Hand - Black Glove, Rose Gold Cover	5060726132510
CVSLMQBLCA	Straight Wrist Medium Left Hand - Black Glove, Carbon Cover	5060726132527
CVSLMQBLTG	Straight Wrist Medium Left Hand - Black Glove, Titan Grey Cover	5060726132534
CVSLMQBLWH	Straight Wrist Medium Left Hand - Black Glove, White Cover	5060726132541
CVSRMQBLRG	Straight Wrist Medium Right Hand - Black Glove, Rose Gold Cover	5060726132558
CVSRMQBLCA	Straight Wrist Medium Right Hand - Black Glove, Carbon Cover	5060726132565
CVSRMQBLTG	Straight Wrist Medium Right Hand - Black Glove, Titan Grey Cover	5060726132572
CVSRMQBLWH	Straight Wrist Medium Right Hand - Black Glove, White Cover	5060726132589
CVSLLQBLCA	Straight Wrist Large Left Hand - Black Glove, Carbon Cover	5060726132596
CVSLLQBLTG	Straight Wrist Large Left Hand - Black Glove, Titan Grey Cover	5060726132602
CVSLLQBLWH	Straight Wrist Large Left Hand - Black Glove, White Cover	5060726132619
CVSRLQBLCA	Straight Wrist Large Right Hand - Black Glove, Carbon Cover	5060726132626
CVSRLQBLTG	Straight Wrist Large Right Hand - Black Glove, Titan Grey Cover	5060726132633
CVSRLQBLWH	Straight Wrist Large Right Hand - Black Glove, White Cover	5060726132640
LNSLSQ	Loan Straight Wrist Left Small Hand	5060726132657
LNSRSQ	Loan Straight Wrist Right Small Hand	5060726132664
LNSLMQ	Loan Straight Wrist Left Medium Hand	5060726132671
LNSRMQ	Loan Straight Wrist Right Medium Hand	5060726132688
LNSLLQ	Loan Straight Wrist Left Large Hand	5060726132695
LNSRLQ	Loan Straight Wrist Right Large Hand	5060726132701

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